FDA 510(k) Premarket Notification

K181949 SYMPHONY™ OCT System

CLEARED

Oct 4, 2018
76 days to decision

K181949 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k181949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Jul 20, 2018
Decision date	Oct 4, 2018
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medos International SARL**
Location	Raynham, MA, US
Contact	Sheree Geller
510(k) history	96 submissions · 96 cleared · 2010-2026